

REMARKS

In the Office Action, the Examiner rejected claims 1-40. Applicants present no amendments by this Response. Claims 1-40 remain pending in the present application. In view of the following remarks, Applicants respectfully request reconsideration and allowance of the pending claims.

Rejections Under Section 102

In the Office Action, the Examiner rejected claims 1-4 under 35 U.S.C. § 102(b) as anticipated by the Kieffer, III et al. reference (U.S. Patent No. 4,380,998; hereinafter “Kieffer”). Specifically, in regard to independent claim 1—the independent claims from which the other rejected claims depend—the Examiner stated as follows:

In regards to claim 1, Kieffer, III et al. disclose a cover for use with an endoscope, comprising: a body 41 having a recesses portion configured to releasably secure to an insertion portion of the endoscope (see Fig. 2).

Office Action mailed June 26, 2005, p. 2 (emphasis in original).

Applicants, however, respectfully submit that a *prima facie* case of anticipation cannot be established in view of Kieffer, because this reference does not disclose all of the features recited in the pending claims. As will be appreciated, anticipation under Section 102 can be found only if a single reference shows exactly what is claimed. *See Titanium Metals Corp. v. Banner*, 227 U.S.P.Q. 773 (Fed. Cir. 1985). For a prior art reference to anticipate under Section 102, every element of the claimed invention must be identically shown in a single reference. *See In re Bond*, 15 U.S.P.Q.2d 1566 (Fed. Cir. 1990). And “[a]ll words in a claim must be considered in judging the patentability of that claim against the prior art.” *In re Wilson*, 165 U.S.P.Q. 494, 496 (C.C.P.A. 1970). Thus, the prior art reference must show the *identical invention “in as complete detail as contained in the ... claim”* to support a *prima facie* case of anticipation. *Richardson v. Suzuki Motor Co.*, 9 U.S.P.Q. 2d 1913, 1920 (Fed. Cir. 1989) (emphasis added).

Additionally, for anticipation, the cited reference must not only disclose all of the recited features but must also disclose the *part-to-part relationships* between these features. See *Lindermann Maschinenfabrik GMBH v. American Hoist & Derrick*, 221 U.S.P.Q. 481, 486 (Fed. Cir. 1984). Accordingly, Applicants need only point to a single element or claimed relationship not found in the cited reference to demonstrate that the cited reference fails to anticipate the claimed subject matter. A *strict correspondence* between the claimed language and the cited reference must be established for a valid anticipation rejection.

As will also be appreciated, during patent examination, the pending claims must be given an interpretation that is reasonable and consistent with the specification. See *In re Prater*, 162 U.S.P.Q. 541, 550-51 (C.C.P.A. 1969); *In re Morris*, 44 U.S.P.Q.2d 1023, 1027-28 (Fed. Cir. 1997); see also M.P.E.P. § 2111 (describing the standards for claim interpretation during prosecution). Indeed, the *specification* is “the primary basis for construing the claims.” See *Phillips v. AWH Corp.*, No. 03-1269, -1286, at 13-16 (Fed. Cir. July 12, 2005) (citations omitted). It is usually dispositive. See *id.* Interpretation of the claims must also be consistent with the interpretation that those skilled in the art would reach. See *In re Cortright*, 49 U.S.P.Q.2d 1464, 1468 (Fed. Cir. 1999); see also M.P.E.P. § 2111. That is, recitations of a claim must be read as they would be interpreted by those of ordinary skill in the art. See *Rexnord Corp. v. Laliram Corp.*, 60 U.S.P.Q.2d 1851, 1854 (Fed. Cir. 2001); see also M.P.E.P. § 2111.01. In summary, an examiner, during prosecution, must interpret a claim recitation as one of ordinary skill in the art would reasonably interpret the claim in view of the specification. See *In re American Academy of Science Tech Center*, 70 U.S.P.Q.2d 1827 (Fed. Cir. 2004).

In the present case, Applicants respectfully submit that Kieffer does not disclose “a body having a recessed portion *configured to releasably secure to an insertion portion of the endoscope*,” as recited in claim 1. (Emphasis added.) Instead, Kieffer discloses a

device that is specifically designed for use with a *frustro-conical* shaped specular device. *See, e.g.*, Kieffer, FIG. 2 (noting the shape of element 22). As such, the Kieffer speculum assembly would simply *slip off* of an endoscope tip it is placed upon. The Kieffer device's body 41 is designed to correspond with the extension 22 it is placed upon, which is also *frustro-conical* in shape. *See id.* at col. 3, ll. 25-30; FIG. 2. Because of this matching in contour, the body 41 and the extension 44 engage at a multitude of locations. However, if the body 41 were to be placed on a cylindrical endoscope tip, the concave and conical body 41 would only come into contact with a circle of points that are tangential to the tip. A degree of contact that is unlikely to maintain engagement between the body 41 and any endoscope tip. Moreover, the facts that body 41 of Kieffer requires a locking lug 53 to maintain engagement with the extension 22 and the fact that that body 41 is formed of a hard material, evidence that the body 41 has a resilient nature that produces an inwardly directed force. *See id.* at col. 3, ll. 25-30; col. 4, ll. 20-29. Resultantly, if the body 41 of Kieffer were to be placed onto an endoscope, the inwardly directed force and the extremely limited areas of contact between the two structures would, based on simple physical relationships, cause the body 41 to slip off any endoscope tip it is placed upon.

Thus, Kieffer does not disclose all of the features recited in the pending claims and, as such, does not anticipate these claims. With the foregoing in mind, Applicants respectfully request reconsideration and allowance of claims 1-4.

Rejections Under Section 103

In the Office Action, the Examiner rejected claims 5-40 under Section 103 as obvious in view of various combinations and permutations of Kieffer, the first Yabe et al. reference (U.S. Patent No. 5,458,133; hereinafter "Yabe '133"), the second Yabe et al. reference (U.S. Patent No. 5,514,074; hereinafter "Yabe '074"), and the Moriyama reference (U.S. Patent App. Pub. No. 2002/0013510; hereinafter "Moriyama"). Applicants address each of these rejections in turn below.

I. Legal Precedent

In summary, Applicants submit that the foregoing Section 103 rejections are not *prima facie* sufficient. The burden of establishing a *prima facie* case of obviousness falls on the Examiner. *Ex parte Wolters and Kuypers*, 214 U.S.P.Q. 735 (PTO Bd. App. 1979). To establish a *prima facie* case, the Examiner must show two things. *See Ex parte Clapp*, 227 U.S.P.Q. 972 (B.P.A.I. 1985). The Examiner must first show that the combination or modification includes *all* of the claimed elements. *See id.* Additionally, the Examiner must present a convincing line of reason as to why one of ordinary skill in the art would have found the claimed invention to have been obvious in light of the teachings of the references. *See id.* Moreover, obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention absent some teaching or suggestion supporting the combination or modification. *See ACS Hospital Systems, Inc. v. Montefiore Hospital*, 221 U.S.P.Q. 929, 933 (Fed. Cir. 1984). Indeed, the mere fact that references *can* be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *See In re Mills*, 16 U.S.P.Q.2d. 1430 (Fed. Cir. 1990).

With particular relevance to the present situation, and as is discussed further below, the Federal Circuit has consistently held that a reference that teaches away from the claimed invention cannot serve to create a *prima facie* case of obviousness. *See In re Gurley*, 31 U.S.P.Q. 2d 1130, 1132 (Fed. Cir. 1994) (noting that it is a useful general rule that “a reference that ‘teaches away’ cannot serve to create a *prima facie* case of obviousness”). Along this vein, an obviousness analysis requires that a reference must be considered in its entirety, including portions that would *lead away* from the claimed invention. *See M.P.E.P. § 2142.02* (8th ed.; Rev. 02). Indeed, “[i]t is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it that will support a given position, to the exclusion of other parts necessary to

the full appreciation of what such reference fairly suggests to one of ordinary skill in the art.” *In re Wesslau*, 147 U.S.P.Q. 391, 393 (C.C.P.A. 1965).

Additionally, in presenting a Section 103 rejection, the Examiner must provide *objective evidence*, rather than subjective belief and unknown authority, of the requisite motivation or suggestion to combine or modify the cited references. See *In re Lee*, 61 U.S.P.Q.2d. 1430 (Fed. Cir. 2002). “Broad conclusory statements standing alone are not ‘evidence’.” *In re Kotzab*, 55 U.S.P.Q. 2d 1314, 1317 (Fed. Cir. 2000). Thus, when prior art references require a selected combination or modification to render obvious a subsequent invention, there must be some reason for the combination or modification *other than the hindsight* gained from the invention itself, i.e., something in the prior art as a whole must suggest the desirability, and thus the obviousness, of making the combination or modification. See *Uniroyal Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 5 U.S.P.Q.2d 1434 (Fed. Cir. 1988). Indeed, the Federal Circuit has warned that the Examiner must not “fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher.” See *In re Dembicza* 50 U.S.P.Q. 2d 52 (Fed. Cir. 1999). (quoting *W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 220 U.S.P.Q. 303, 313 (Fed. Cir. 1983)). Moreover, avoiding hindsight reconstruction is especially important regarding less technologically complex inventions, where the very ease which the invention can be understood may prompt one to employ such hindsight. See *id.*

As discussed above, in determining the differences between the prior art and the claims, the question under Section 103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious. See *Stratoflex, Inc. v. Aeroquip Corp.*, 218 U.S.P.Q. 871 (Fed. Cir. 1983). Thus, the Examiner must not look at each element of a claim individually, but rather the claims should be viewed as a tapestry comprising the recited elements. Thus, “it is

impermissible, however, to simply engage in a hindsight reconstruction of the claimed invention, *using the applicant's structure as a template* and selecting elements from references to fill the gaps." *In re Gorman*, 18 U.S.P.Q. 2d 1885, 1888 (Fed. Cir. 1991) (emphasis added). Simply put, what may seem logical to combine in retrospect and after viewing an applicant's invention is not obvious unless the cited references, without benefit of this hindsight, teach what is claimed. *See In re Zurko*, 42 U.S.P.Q.2d 1476, 1479 (stating "[w]hile in retrospect, looking at applicants' invention, it might seem logical to perform a repeat-back in the UNIX system over a trusted line, neither UNIX nor FILER2 teaches communications with the user of a trusted pathway," as is recited in the claim in question). In summary, a valid Section 103 rejection must articulate and support with objective evidence a line of reasoning that establishes why one of ordinary skill in the art, with no knowledge of an applicant's intention, would make the combination in the manner claimed. *See In re Kotzab*, 55 U.S.P.Q. at 1318 (Fed. Cir. 2000).

With the foregoing legal precedent in mind, Applicants respectfully assert that the pending claims are not obvious in view of the cited references, whether taken alone or together.

II. First Rejection Under Section 103

In the Office Action, the Examiner rejected dependent claims 6 and 7 under Section 103(a) as obvious in view of Kieffer and Yabe '074. Applicants, however, respectfully submit that these claims are patentable not only by virtue of their dependencies upon allowable independent claim 1, but also by virtue of the additional features recited therein. Indeed, the Examiner relies primarily on the Kieffer reference, and Yabe '074 does not obviate the deficiencies of Kieffer discussed above. With the foregoing in mind, Applicants respectfully request reconsideration and allowance of claims 6 and 7.

III. Second Rejection Under Section 103

In the Office Action, the Examiner rejected claims 5, 8-13, 15-18, 22-29, and 31-36 under Section 103 as obvious in view of Kieffer and Yabe '133. In rejecting these claims, the Examiner stated as follows:

Kieffer, III et al. disclose a cover having a body 41 having a recessed portion configured to releasably secure to an insertion portion of the endoscope but is silent with respect to the body including an indicium configured to indicate a contamination condition. Yates et al. teach of an analogous cover for an endoscope wherein an indication device for indicating whether or not an apparatus should handle a clean area in a sterile state or other area is provided on each of the components (see Col. 4, Lines 36-67). Furthermore, Yates et al [sic] teach of using the indicia to help an operator recognize whether he is working with a sterile apparatus or a contaminated apparatus. The indication means for indicating whether an area is a clean or general area of the cover type endoscope apparatus is not limited to being a blue or yellow tape. Rather, in the indication means, colors to be displayed and display area and display areas may be appropriately combined. Also, the indication means is not limited to being a color display, but symbols or characters may be used, or a combination of symbols or characters may be used. It would have been obvious to one skilled in the art at the time the invention was made to apply an indicium to the appropriate covers of Kieffer, III et al. in order to allow easy recognition of the contamination status of the apparatus as taught by Yabe et al. The apparatus of Kieffer, III et al. and Yabe et al. is [sic] is inherently capable of performing the recited method claims.

Office Action mailed July 26, 2005. Applicants, however, respectfully submit that a *prima facie* case of obviousness has not been established with respect to the pending claims.

First, Applicants respectfully submit that not all features of the pending claims are disclosed by the cited reference combination. For example, independent claims 1, 5, 22,

27, 31, and 36—which are all of the independent claims in the present application—each relates to, in a general sense, a protective tip that can be placed on an endoscope. Specifically, these claims recite as follows:

Claim 1: “a body having a recessed portion configured to releasably secure to an insertion portion of the endoscope;”

Claim 15: “first and second cover members...configured to releasably secure to the probe end;”

Claim 22: “securing a first cover member...to the probe portion...[and] securing a second cover member...to the probe portion;”

Claim 27: “a first means for covering the probe portion...and a second means for covering the probe portion;”

Claim 31: “a cover configured to releasably secure to the probe portion;” and

Claim 36: “cover being configured to receive the insertion portion...and...the second cover being configured to receive the insertion portion.”

By contrast, as discussed above, Kieffer discloses an assembly having a frustro-conical shape that inherently would slip off of the end of a endoscope tip, because the tip is cylindrical in nature. Indeed, nothing in Kieffer suggests, let alone teaches, that the Kieffer device, which is for a particular type of speculum, can be appropriately placed with respect to the tip of an endoscope. Moreover, Applicants respectfully submit that noting in Yabe ‘133 obviates the deficiencies of Kieffer.

Furthermore, the cited references, taken alone or in combination, do not disclose multiple covers, each cover having a different indicia representative of different conditions, as relates to, in a general sense, independent claims 15, 22, 27, and 36. Specifically, these claims recite as follows:

Claim 15: “the first cover member comprises a first indicium indicative of a first endoscope condition and the second cover member comprises a second indicium indicative of a second endoscope condition;”

Claim 22: “a first cover member having a first indicium indicative of a first endoscope condition to the probe portion...and a second cover member having a second indicium indicative of a second endoscope condition to the probe portion;”

Claim 27: “a first means for covering the probe portion, thereby indicating a first status of the endoscope; and a second means for covering the probe portion thereby indicating a second status of the endoscope;” and

Claim 36: “a first cover having a first indicia indicative of a used state and a need for sterilization...and a second cover having a second indicia indicative of a sterilized state.”

By contrast, Yabe ‘133—the reference the Examiner relies upon for the foregoing features (*see* Office Action mailed July 26, 2005, pp. 3-4)—relates to indication means 30 that are dedicated to indicating a *permanent* characteristic of a portion of the endoscope and, thus, fail to teach the transitioning between conditions. In Yabe ‘133, the various colored tapes are designed to indicate the level of cleaning required for that given part. *See* Yabe ‘133, col. 4, ll. 37-57. For instance, the blue tape 30B is placed on an insertion cover portion 3a to indicate that this area is a sterile area that requires thorough cleaning. Conversely, a yellow tape indicates a general area, for which an as thorough cleaning is not required. *See id.* Thus, the tape 30B, in contrast to the Examiner’s assertions, does not indicate that the cover portion 3a needs cleaning. *See id.* In fact, whether the cover portion 3a has been inserted into a patient or not, the tape 30B will be blue. *See id.* The indicia of Yabe ‘133 is dedicated to the part it is employed with, not the parts condition. In other words, the connection cable 47a will always have a yellow label, and the operation portion cover 3b will always have a blue label, independent of the operating status or condition of the device.

Secondly, Applicants respectfully submit that a proper motivation for combination has not been articulated. As discussed above, the Examiner has misinterpreted Yabe '133 by asserting that "Yates et al. [sic] teach of using the indicia to help an operator recognize whether he is working with a sterile apparatus or a contaminated apparatus." See Office Action mailed July 26, 2005, p. 4. Again, Yabe '133 simply provides indicia to indicate that certain parts of an endoscope are better served by more thorough cleanings. A user would not be able to determine if a part is contaminated or not by viewing the labels of Yabe '133. In view of this, Applicants respectfully submit that the Examiner has not provided objective evidence that demonstrates why the cited references could be combined to reach the pending claims. In fact, even if it is assumed, *arguendo*, that the cited references disclose all of the claimed features of the pending claims, the lack of objective evidence for combining the cited references evidences that the Examiner has employed impermissible hindsight reconstruction to reach the pending claims. In other words, the Examiner has employed Applicants' disclosure as a roadmap for combining the cited references.

Based on the foregoing, Applicants respectfully submit that a *prima facie* case of obviousness has not been established with respect to the pending claims. Therefore, Applicants respectfully request reconsideration and allowance of claims , 8-13, 15-18, 22-29, and 31-36.

IV. Third Rejection Under Section 103

In the Office Action, dependent claims 19-21 and 37-40 were rejected under Section 103 as obvious in view of Kieffer, Yabe '133, and Moriyama. Applicants, however, respectfully submit that these claims, which depend from independent claims 15 and 36, are patentable by virtue of their respective dependencies on allowable based claims, and also by virtue of the additional features recited therein. Moreover, Applicants respectfully submit that Moriyama does not obviate the deficiencies of Kieffer and Yabe.

‘133 discussed above. Therefore, Applicants respectfully request reconsideration and allowance of these claims.

Conclusion

Applicants respectfully submit that all pending claims should be in condition for allowance. However, if the Examiner believes certain amendments are necessary to clarify the present claims or if the Examiner wishes to resolve any other issues by way of a telephone conference, the Examiner is kindly invited to contact the undersigned attorney at the telephone number indicated below.

Respectfully submitted,



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